JUL 25 2012

**Special 510(k)**
**Device Modification of Greiner VACUETTE® SAFETY Infusion Set (K080235)**

## 3 510(k) SUMMARY

June 26, 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

The assigned 510(k) number is: _____.

CONTACT:

Manfred Abel
Greiner Bio-One North America, Inc.
P.O Box 1026
Monroe, NC 28111

NAME OF DEVICES:

| | |
|---|---|
| Trade Name: | **VACUETTE®** SAFETY Infusion Set |
| Common Name: | IV Fluid Transfer Set |
| Classification Name: | Hypodermic Single Lumen Needle |

PREDICATE DEVICE:
Greiner **VACUETTE®** SAFETY Infusion Set – K080235 (FDA cleared 4/24/2008)
Greiner **VACUETTE®** SAFETY Blood Collection Set – K011786 (FDA cleared 7/12/2001)

DEVICE DESCRIPTION:

**Intended Use**: The VACUETTE® SAFETY Infusion Set is a single-use, sterile, winged blood collection needle bonded to a flexible tubing with a luer connector. The VACUETTE® SAFETY Infusion Set is used for blood collection and/or the short-term infusion of intravenous fluids. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

**Product Description**: The Greiner VACUETTE® SAFETY Infusion Set is a single-use, sterile, winged infusion and blood collection needle bonded to flexible tubing with a female luer adapter.

The VACUETTE® SAFETY Infusion Set is used for short-term administration of intravenous fluids and/or for blood collection. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. The product is to be used by appropriately trained healthcare professionals only in accordance with manufacturer's instructions. It can be used in conjunction with an intravascular administration set or with a syringe or other device in order to administer fluids.

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The safety feature is easily operated through the release of a latch mechanism whereby the user slides a winged cover over the needle, as it is removed from the patient. Once the needle is covered, the safety cover locks in place.

The devices are packaged as sterile and are labeled for single use only. There is no ability to clean and reuse these devices because the safety feature cannot be deactivated without bending the needle and rendering it unusable.

SUBSTANTIAL EQUIVALENCE:

The Greiner **VACUETTE®** SAFETY Infusion Set is substantially equivalent to the predicate device in fundamental scientific technology, intended use, and materials.

This Special 510(k) is submitted for a device modification to the Greiner **VACUETTE®** SAFETY Infusion Set (K080235; FDA cleared 4/24/2008) to include additional needle gauges and tubing length.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 25 2012

Greiner Bio-One North America, Incorporated
C/O Ms. Judith Smith
Principal
P.O Box 103
Baldwin, Maryland 21013

Re: K121908
Trade/Device Name: VACUETTE® SAFETY Infusion Set
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: June 28, 2012
Received: June 29, 2012

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

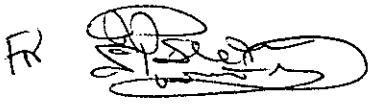
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K121908

Device Name: **VACUETTE®** SAFETY Infusion Set

Indication For Use:

The VACUETTE® SAFETY Infusion Set is a single-use, sterile, winged blood collection needle bonded to a flexible tubing with a luer connector. The VACUETTE® SAFETY Infusion Set is used for blood collection and/or the short-term infusion of intravenous fluids. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for RZC July 20, 2012

Division Sign-Off
Office of Device Evaluation

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121908

510(k)_____